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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

EINSMANN, JULIET CAROLINE

ART UNIT PAPER NUMBER

1655

DATE MAILED: 12/04/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/284,697

Applicant(s)

GRUBER ET AL.

Examiner

Juliet C Einsmann

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(d).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-58 is/are pending in the application.
- 4a) Of the above claim(s) 29,30,36-38 and 42-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27,28,31-35,39-41,57 and 58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. This action is written in response applicant's correspondence submitted 9/24/01, paper number 16. Claims 27 and 33 have been amended and claims 57-58 have been added. Claims 27-58 are pending, claims 29, 30, 36-38, and 42-46 are withdrawn from prosecution because they are drawn to non-elected inventions. An action on claims 27, 28, 31-35, 39-41, 57, and 58 follows. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is FINAL.**

Election/Restrictions

2. This application contains claims 29, 30, 36-38, and 42-46 drawn to an invention nonelected without traverse in Paper No. 12. Furthermore, the elected claims encompass subject matter drawn to more than one invention. As a proper response to this office action, the claims must be amended to cancel non-elected subject matter. Claims 27, 28, 31-35, 39-41, 57, and 58 must be amended to designate the elected subject matter, that is nucleic acids encoding pancreatic lipase, methods for obtaining pancreatic lipase, and genetically transformed plants comprising nucleic acids encoding pancreatic lipase.

Specification

3. The substitute specification filed 9/24/01 is acceptable and has been entered.
4. The new sequence listing, both paper copy and CRF have been entered.
5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However,

this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reason(s):

There are numerous nucleic acid and amino acid sequences recited in the specification that are not properly labeled with sequence identifiers.

In order to comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825), Applicant must submit amendments properly labeling the sequences with identifiers. If necessary, applicant must submit a new sequence listing, a new CRF and a letter stating that the content of the paper and computer readable copies are the same.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 27-28, 31-35, 39-41, and 57-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willmitzer *et al.* (WO 92/01042) in view of Lowe *et al.* (J. of Biological Chemistry, 1989, 264 (33): 20042-20048).

This rejection is reiterated for the claims as amended and applied to newly added claims 57 and 58.

Willmitzer *et al.* teach transgenic plants expressing industrial enzymes, and methods for the production of such plants. The industrial enzymes suggested by Willmitzer *et al.* for use in these methods include lipases (p. 6, line 21). They specifically teach that the DNA sequence

encoding the enzyme of interest should be under the control of a promoter such as the 35s RNA promoter from cauliflower mosaic virus (p. 4, lines 28-29) and a terminator such as the 35s RNA terminator from cauliflower mosaic virus (p. 5, line 18). Willmitzer *et al.* further suggest that the expression constructs include a DNA sequence encoding a leader peptide capable of directing the transport of the expressed enzyme to a specific cellular compartment (for example vacuoles) (p. 5, lines 22-25). Willmitzer *et al.* teach a variety of plants useful for the introduction of the enzyme, including tobacco, potato, tomato, pea, soy, and cereals (p. 7, lines 19-21), and further teach that either the entire plant or parts thereof may be useful for animal feeds (p. 7, lines 10-13). Willmitzer *et al.* teach vectors for the integration of foreign DNA into plant cells and the introduction of these vectors into *Agrobacterium* species (p. 9, line 28-p. 9, line 19). Willmitzer *et al.* further teach methods for the recovery of the transgenic enzymes, and such method steps include an extraction step (p. 12, lines 8-16).

Willmitzer *et al.* do not exemplify these methods with a pancreatic lipase.

Lowe *et al.* teach recombinant nucleic acids coding for human pancreatic lipase (Fig. 2).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have inserted the coding sequence taught by Lowe *et al.* into a plant using the methods taught by Willmitzer *et al.* The ordinary practitioner would have been motivated to express a nucleic acid encoding a lipase in a plant as taught by Willmitzer *et al.* because Willmitzer *et al.* expressly teach that the production of enzymes in plants overcomes two major obstacles in industrial enzyme production, "Firstly, higher plants have biosynthetic capacity to perform the requisite post-translational modifications occurring in eukaryotic cells of mammalian or other origin. Secondly, transgenic plants grown in the field need very little extra

energy for growth (and hence for the production of proteins such as industrial enzymes) and furthermore do not give rise to any major problems with respect to waste management (p. 4, lines 10-18).” Willmitzer *et al.* provide the necessary suggestion and direction to motivate the production of lipases in plants, and thus, in the absence secondary considerations such as unexpected results, the claimed invention is obvious over the prior art.

Response to Remarks

Applicant argues that Willmitzer *et al.* neither describe nor suggest a nucleotide sequence that encodes a pharmaceutically active pancreatic lipase, and that by defining the enzymes as industrial they teach away from using the nucleic acid sequences in plants to encode a lipase that would be suited for use as a pharmaceutical composition or a functional food. First, applicant is correct in stating that Willmitzer *et al.* do not teach a nucleic acid encoding a pancreatic lipase, the nucleic acid encoding a human pancreatic lipase is provided by Lowe *et al.* (see rejection above). In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In addition, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In the instant case, nucleic acid taught by the combination of Willmitzer *et al.* with Lowe *et al.* is no

different from the instantly claimed nucleic acid molecule (see MPEP 2111.02). The limitation added to base claim 27 has no apparent structural implication for the DNA sequence being claimed. Similarly, with regard to the method of obtaining the pancreatic lipase (claim 33), there is no obvious structural imposition is found in amendment to the claim. A plant made by the methods of Willmitzer *et al.* in view of Lowe *et al.* for "industrial purposes" seems to be equally suited for in recovering a human pancreatic lipase useful as a functional food or in a pharmaceutical composition.

Finally, it is noted that the language of the claim is quite broad, requiring that the element (the lipase) or a derivative of the element is suited for use as a pharmaceutical or functional food. Thus, even after expression of the nucleic acid, the claim allows for any modification of the expressed product to obtain a derivative which is suitable for the recited intended use. Once again, the instant amendment does not appear to add any structural limitations which differentiate the claims from the cited teachings in the prior art.

Applicant further argues that Willmitzer *et al.* enumerate lipases as one of 26 possible industrial enzymes, and contain no suggestion to select lipases over other enzymes and no particular suggestion to select a pancreatic lipase, or specifically a human pancreatic lipase. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir.

1992). In this case, a clear motivation to use the expression methods taught by Willmitzer *et al.* is provided in the rejection. Applicant argues that there is no specific motivation to select the instant sequence, however, applicant is reminded that MPEP 2123 teaches that "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments." In the instant case, the Willmitzer *et al.* reference must be considered for it's teaching that the methodology is useful for expressing lipases, which are known to be enzymes with industrial applicability, and which Willmitzer *et al.* include in a list of such enzymes. Thus, in light of the teachings of Willmitzer *et al.* that their method is useful for the production of lipases, and the teachings of Lowe *et al.* of the nucleic acid sequence of such enzymes, there is indeed motivation to produce plants that express the any lipase including those taught by Lowe *et al.*

Finally, applicant argues that Lowe *et al.* is not analogous art with respect to Willmitzer *et al.* However this is not persuasive. Although the two references have different over all foci, they are indeed analogous art. Willmitzer *et al.* is concerned with the production of enzymes, specifically stating that lipase is one of the options. Lowe *et al.*, while they work to dicern the mechanism of lipase, do so by isolating the nucleic acid encoding the lipase and then using that nucleic acid to translate the lipase. Thus, both references are concerned with the same overall problem, that problem being the study and use of lipases.

For these reasons, the rejection is maintained.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 27-28, 31-35, 39-41, and 57-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27-28, 31-35, 39-41, and 57-58 are indefinite over the recitation of "suited" because to be "suited" is a latent characteristic and the claims do not set forth the criteria by which to determine how or when a lipase is suited for the specified uses. That is, it is not clear whether the recited elements have the potential to be used as pharmaceuticals or functional foods or do in are in fact pharmaceuticals or functional foods.

Claims 27-28, 31-35, 39-41, and 57-58 are indefinite over the recitation of "functional food" because it is not clear what is required of a food to be "functional."

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

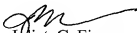
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


JEFFREY FREDMAN
PRIMARY EXAMINER


Juliet C. Einsmann
Examiner
Art Unit 1655

November 29, 2001